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(71) Applicant *(for all designated States except US)*: **CAMERON HEALTH, INC.** [US/US]; 924-A Calle Negocio, San Clemente, CA 92673 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BARDY, Gust, H.** [US/US]; 2518 Constance Drive West, Seattle, WA 98199 (US). **CAPPATO, Riccardo** [IT/IT]; Via Fluvio Testi, 22, I-44100 Ferrara (IT).

(74) Agents: **PETTIT, Jonathan, L.** et al.; Brobeck, Phleger & Harrison, 12390 El Camino Real, San Diego, CA 92130 (US).

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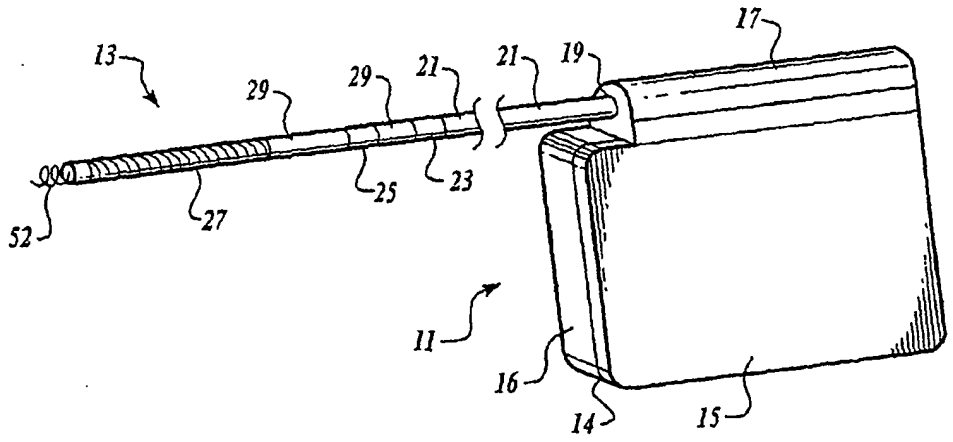

(57) Abstract: A subcutaneous implantable cardioverter-defibrillator is disclosed which has an electrically active canister which houses a source of electrical energy, a capacitor, and operational circuitry that senses the presence of potentially fatal heart rhythms. At least one subcutaneous electrode that servers as the opposite electrode from the canister is attached to the canister via a lead system Cardioversion-defibrillation energy is delivered when the operaional circuitry senses a potentially fatal heart rhythm. There are no transvenous, intracardiac, or epicardial electrodes. A method of subcutaneously implanting the cardioverter-defibrillator is also disclosed as well as a kit for conducting the method.

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SUBCUTANEOUS ONLY IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR AND OPTIONAL PACER

Inventors:

Gust Bardy, M.D.

FIELD OF THE INVENTION

The present invention relates to an apparatus and method for performing electrical cardioversion/defibrillation and optional pacing of the heart via a totally subcutaneous non-transvenous system.

CROSS-REFERENCE TO RELATED APPLICATION(S)

This application is related to a PCT patent application entitled Unitary Subcutaneous Only Implantable Cardioverter-Defibrillator and Optional Pacer with the same inventors herein and filed on the same day as this application. The entire disclosure of the related application is herein incorporated by reference.

BACKGROUND OF THE INVENTION

Defibrillation/cardioversion is a technique employed to counter arrhythmic heart conditions including some tachycardias in the atria and/or ventricles. Typically, electrodes are employed to stimulate the heart with electrical impulses or shocks, of a magnitude substantially greater than pulses used in cardiac pacing.

Defibrillation/cardioversion systems include body implantable electrodes and are referred to as implantable cardioverter/defibrillators (ICDs). Such electrodes can be in the form of patches applied directly to epicardial tissue, or at the distal and regions of intravascular catheters, inserted into a selected cardiac chamber. U.S. Pat. Nos. 4,603,705, 4,693,253, 4,944,300, 5,105,810, the disclosures of which are all incorporated herein by reference, disclose intravascular or transvenous electrodes, employed either alone or in combination with an epicardial patch electrode. Compliant epicardial defibrillator electrodes are disclosed in U.S. Pat. Nos. 4,567,900 and 5,618,287, the disclosures of which are incorporated herein by reference. A sensing epicardial electrode configuration

is disclosed in U.S. Pat No. 5,476,503, the disclosure of which is incorporated herein by reference.

In addition to epicardial and transvenous electrodes, subcutaneous electrode systems have also been developed. For example, U.S. Patent Nos. 5,342,407 and 5,603,732, the disclosures of which are incorporated herein by reference, teach the use of a pulse monitor/generator surgically implanted into the abdomen and subcutaneous electrodes implanted in the thorax. This system is far more complicated to use than current ICD systems using transvenous lead systems together with an active can electrode and therefore it has no practical use. It has in fact never been used because of the surgical difficulty of applying such a device (3 incisions), the impractical abdominal location of the generator and the electrically poor defibrillation aspects of such a system.

Recent efforts to improve the efficiency of ICDs have led manufacturers to produce ICDs which are small enough to be implanted in the pectoral region. In addition, advances in circuit design have enabled the housing of the ICD to form a subcutaneous electrode. Some examples of ICDs in which the housing of the ICD serves as an optional additional electrode are described in U.S. Pat. Nos. 5,133,353, 5,261,400, 5,620,477, and 5,658,321 the disclosures of which are incorporated herein by reference.

ICDs are now an established therapy for the management of life threatening cardiac rhythm disorders, primarily ventricular fibrillation (V-Fib). ICDs are very effective at treating V-Fib, but are therapies that still require significant surgery.

As ICD therapy becomes more prophylactic in nature and used in progressively less ill individuals, especially children at risk of cardiac arrest, the requirement of ICD therapy to use intravenous catheters and transvenous leads is an impediment to very long term management as most individuals will begin to develop complications related to lead system malfunction sometime in the 5-10 year time frame, often earlier. In addition, chronic transvenous lead systems, their reimplantation and removals, can damage major cardiovascular venous systems and the tricuspid valve, as well as result in life threatening perforations of the great vessels and heart. Consequently, use of transvenous lead systems, despite their many advantages, are not without their chronic patient management limitations in those with life expectancies of >5 years. The problem of lead complications

is even greater in children where body growth can substantially alter transvenous lead function and lead to additional cardiovascular problems and revisions. Moreover, transvenous ICD systems also increase cost and require specialized interventional rooms and equipment as well as special skill for insertion. These systems are typically implanted by cardiac electrophysiologists who have had a great deal of extra training.

In addition to the background related to ICD therapy, the present invention requires a brief understanding of automatic external defibrillator (AED) therapy. AEDs employ the use of cutaneous patch electrodes to effect defibrillation under the direction of a bystander user who treats the patient suffering from V-Fib. AEDs can be as effective as an ICD if applied to the victim promptly within 2 to 3 minutes.

AED therapy has great appeal as a tool for diminishing the risk of death in public venues such as in air flight. However, an AED must be used by another individual, not the person suffering from the potentially fatal rhythm. It is more of a public health tool than a patient-specific tool like an ICD. Because >75% of cardiac arrests occur in the home, and over half occur in the bedroom, patients at risk of cardiac arrest are often alone or asleep and can not be helped in time with an AED. Moreover, its success depends to a reasonable degree on an acceptable level of skill and calm by the bystander user.

What is needed therefore, especially for children and for prophylactic long term use, is a combination of the two forms of therapy which would provide prompt and near-certain defibrillation, like an ICD, but without the long-term adverse sequelae of a transvenous lead system while simultaneously using most of the simpler and lower cost technology of an AED. We call such a device a sub-cutaneous only ICD (S-ICD) and is described in detail below.

SUMMARY OF THE INVENTION

The preferred embodiment for the subcutaneous only ICD (S-ICD) with optional pacing consists of five basic components: 1) an electrically active canister housing a battery supply, capacitor and operational circuitry wherein the housing serves as an electrode and replaces one conventional lead of the prior art systems; 2) one or more subcutaneous combined high voltage/sense/pace electrodes emanating from the S-ICD

housing; 3) sense circuitry suitable to an ICD or AED V-FIB detection algorithm; 4) an application system for simple insertion of the subcutaneous lead; and 5) a cutaneous test system designed to estimate the best location of the S-ICD for each patient. Therefore, no transvenous lead system is necessary, eliminating a significant impediment to broader scale prophylactic use and especially use in children.

The active canister housing will provide energy and voltage intermediate to that available with ICD and AEDs. The typical maximum voltage necessary for ICDs using most biphasic waveforms is approximately 750V and associated maximum energy of approximately 40J. The typical maximum voltage necessary for AEDs is approximately 2000-5000V with an associated maximum energy of approximately 150-360J. The S-ICD of the present invention will use voltages in the range of 800 to 2000V and associated with energies of approximately 40-150J. The canister could be employed as either a cathode or an anode.

In the preferred embodiment only one subcutaneous high voltage electrode, of opposite polarity to the canister, will be used but no limit is placed on the number of subcutaneous electrodes that may be required to achieve optimal S-ICD function. The subcutaneous electrode, composed of silicone or polyurethane insulation, will have a minimum of 1 electrode but, in the preferred embodiment, will have 3: a high voltage, low-impedance coil electrode approximately 5-10 cm length and two low voltage, high impedance sense electrodes at the tip. The spacing of the sense electrodes will be approximately 4 cm to provide a reasonable QRS signal from a subcutaneous extracardiac sampling location but may be of a variable length to allow for sense optimization. In the preferred embodiment, the sense electrodes are placed proximal to the high voltage lead, contrary to typical transvenous ICD lead systems, but alternative locations are allowed.

The sense circuitry in the preferred embodiment is designed to be highly sensitive and specific to the presence or absence of life threatening ventricular arrhythmias only. Features of the detection algorithm are programmable but the algorithm is focused on the detection of V-Fib and high rate ventricular tachycardia (V-Tach) of greater than 240 bpm. This type of cardioverter-defibrillator is not necessarily designed to replace ICD therapy for those with pre-identified problems of V-Tach/V-Fib or even atrial fibrillation, but is

particularly geared to use as a prophylactic, long-term device, used for the life of the patient at risk of his/her first V-Fib/V-Tach event. The device of the present invention may infrequently be used for an actual life threatening event but can be employed in large populations of individuals at modest risk and with modest cost by physicians of limited experience. Consequently, the preferred embodiment of the present invention focuses only on the detection and therapy of the most malignant rhythm disorders. As part of the detection algorithm's applicability to children, the upper rate range is programmable upward for use in children, who are known to have more rapid supraventricular tachycardias as well as more rapid ventricular tachycardias compared to adults.

The incision to apply the device of the present invention can be anywhere on the thorax although in the preferred embodiment, the device of the present invention will be applied in the left anterior mid-clavicular line approximately at the level of the mammary crease beneath the left areolas. The S-ICD can be placed subcutaneously as any ICD is currently placed. One critical difference is that the high voltage/sense lead is placed totally subcutaneously with a specially designed curved introducer set, through which local anesthetic can be delivered, if necessary, following by insertion of the lead system via the same incision used for generator insertion. The lead, however, unlike the generator, is directed laterally and posteriorly for positioning of the lead in the posterior thoracic region, ideally in the left posterior axillary line at the level of the inferior scapula tip. Such a lead position will allow for a good transthoracic current delivery vector as well as positioning of the proximally positioned sense bipole in a good location for identification of the QRS. There is no transvenous component.

The final component of the S-ICD is a cutaneous test electrode system designed to simulate the subcutaneous high voltage shock electrode system as well as the QRS cardiac rhythm detection system. This test electrode system is comprised of a cutaneous patch electrode of similar surface area and impedance to that of the S-ICD canister itself together with a cutaneous strip electrode comprising a defibrillation strip as well as two button electrodes for sensing of the QRS. Several cutaneous strip electrodes are available to allow for testing various bipole spacings to optimize signal detection in order to allow

for variable sense bipole spacings on leads of different length and electrode spacing and configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the invention, reference is now made to the drawings where like numerals represent similar objects throughout the figures where:

FIG. 1 is a schematic view of a Subcutaneous ICD (S-ICD) of the present invention;

FIG. 2 is a schematic view of an alternate embodiment of a subcutaneous electrode of the present invention;

FIG. 3 is a schematic view of an alternate embodiment of a subcutaneous electrode of the present invention;

FIG. 4 is a schematic view of the S-ICD and lead of FIG. 1 subcutaneously implanted in the thorax of a patient;

FIG. 5 is a schematic view of the S-ICD and lead of FIG. 2 subcutaneously implanted in an alternate location within the thorax of a patient;

FIG. 6 is a schematic view of the S-ICD and lead of FIG. 3 subcutaneously implanted in the thorax of a patient;

FIG. 7 is a schematic view of the method of making a subcutaneous path from the preferred incision and housing implantation point to a termination point for locating a subcutaneous electrode of the present invention;

FIG. 8 is a schematic view of an introducer set for performing the method of lead insertion of any of the described embodiments;

FIG. 9 is a schematic view of an alternative S-ICD of the present invention illustrating a lead subcutaneously and serpiginously implanted in the thorax of a patient for use particularly in children;

FIG. 10 is a schematic view of an alternate embodiment of an S-ICD of the present invention;

FIG. 11 is a schematic view of the S-ICD of FIG. 10 subcutaneously implanted in the thorax of a patient;

FIG. 12 is a schematic view of yet a further embodiment where the canister of the S-ICD of the present invention is shaped to be particularly useful in placing subcutaneously adjacent and parallel to a rib of a patient; and

FIG. 13 is a schematic of a different embodiment where the canister of the S-ICD of the present invention is shaped to be particularly useful in placing subcutaneously adjacent and parallel to a rib of a patient.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to FIG. 1, the S-ICD of the present invention is illustrated. The S-ICD consists of an electrically active canister 11 and a subcutaneous electrode 13 attached to the canister. The canister has an electrically active surface 15 that is electrically insulated from the electrode connector block 17 and the canister housing 16 via insulating area 14. The canister can be similar to numerous electrically active canisters commercially available in that the canister will contain a battery supply, capacitor and operational circuitry. Alternatively, the canister can be thin and elongated to conform to the intercostal space. The circuitry will be able to monitor cardiac rhythms for tachycardia and fibrillation, and if detected, will initiate charging the capacitor and then delivering cardioversion/defibrillation energy through the active surface of the housing and to the subcutaneous electrode. Examples of such circuitry are described in U.S. Patent Nos. 4,693,253 and 5,105,810, the entire disclosures of which are herein incorporated by reference. The canister circuitry can provide cardioversion/defibrillation energy in different types of waveforms. In the preferred embodiment, a 100 uF biphasic waveform is used of approximately 10-20 ms total duration and with the initial phase containing approximately 2/3 of the energy, however, any type of waveform can be utilized such as monophasic, biphasic, multiphasic or alternative waveforms as is known in the art.

In addition to providing cardioversion/defibrillation energy, the circuitry can also provide transthoracic cardiac pacing energy. The optional circuitry will be able to monitor the heart for bradycardia and/or tachycardia rhythms. Once a bradycardia or tachycardia rhythm is detected, the circuitry can then deliver appropriate pacing energy at appropriate intervals through the active surface and the subcutaneous electrode. Pacing stimuli will be

biphasic in the preferred embodiment and similar in pulse amplitude to that used for conventional transthoracic pacing.

This same circuitry can also be used to deliver low amplitude shocks on the T-wave for induction of ventricular fibrillation for testing S-ICD performance in treating V-Fib as is described in U.S. Patent No. 5,129,392, the entire disclosure of which is hereby incorporated by reference. Also the circuitry can be provided with rapid induction of ventricular fibrillation or ventricular tachycardia using rapid ventricular pacing. Another optional way for inducing ventricular fibrillation would be to provide a continuous low voltage, i.e., about 3 volts, across the heart during the entire cardiac cycle.

Another optional aspect of the present invention is that the operational circuitry can detect the presence of atrial fibrillation as described in Olson, W. et al. "Onset And Stability For Ventricular Tachyarrhythmia Detection in an Implantable Cardioverter and Defibrillator," Computers in Cardiology (1986) pp. 167-170. Detection can be provided via R-R Cycle length instability detection algorithms. Once atrial fibrillation has been detected, the operational circuitry will then provide QRS synchronized atrial defibrillation/cardioversion using the same shock energy and waveshape characteristics used for ventricular defibrillation/ cardioversion.

The sensing circuitry will utilize the electronic signals generated from the heart and will primarily detect QRS waves. In one embodiment, the circuitry will be programmed to detect only ventricular tachycardias or fibrillations. The detection circuitry will utilize in its most direct form, a rate detection algorithm that triggers charging of the capacitor once the ventricular rate exceeds some predetermined level for a fixed period of time: for example, if the ventricular rate exceeds 240 bpm on average for more than 4 seconds. Once the capacitor is charged, a confirmatory rhythm check would ensure that the rate persists for at least another 1 second before discharge. Similarly, termination algorithms could be instituted that ensure that a rhythm less than 240 bpm persisting for at least 4 seconds before the capacitor charge is drained to an internal resistor. Detection, confirmation and termination algorithms as are described above and in the art can be modulated to increase sensitivity and specificity by examining QRS beat-to-beat uniformity, QRS signal frequency content, R-R interval stability data, and signal

amplitude characteristics all or part of which can be used to increase or decrease both sensitivity and specificity of S-ICD arrhythmia detection function.

In addition to use of the sense circuitry for detection of V-Fib or V-Tach by examining the QRS waves, the sense circuitry can check for the presence or the absence of respiration. The respiration rate can be detected by monitoring the impedance across the thorax using subthreshold currents delivered across the active can and the high voltage subcutaneous lead electrode and monitoring the frequency in undulation in the waveform that results from the undulations of transthoracic impedance during the respiratory cycle. If there is no undulation, then the patent is not respiring and this lack of respiration can be used to confirm the QRS findings of cardiac arrest. The same technique can be used to provide information about the respiratory rate or estimate cardiac output as described in U.S. Patent Nos. 6,095,987, 5,423,326, 4,450,527, the entire disclosures of which are incorporated herein by reference.

The canister of the present invention can be made out of titanium alloy or other presently preferred electrically active canister designs. However, it is contemplated that a malleable canister that can conform to the curvature of the patient's chest will be preferred. In this way the patient can have a comfortable canister that conforms to the shape of the patient's rib cage. Examples of conforming canisters are provided in U.S. Patent No. 5,645,586, the entire disclosure of which is herein incorporated by reference. Therefore, the canister can be made out of numerous materials such as medical grade plastics, metals, and alloys. In the preferred embodiment, the canister is smaller than 60 cc volume having a weight of less than 100 gms for long term wearability, especially in children. The canister and the lead of the S-ICD can also use fractal or wrinkled surfaces to increase surface area to improve defibrillation capability. Because of the primary prevention role of the therapy and the likely need to reach energies over 40 Joules, a feature of the preferred embodiment is that the charge time for the therapy, intentionally be relatively long to allow capacitor charging within the limitations of device size. Examples of small ICD housings are disclosed in U.S. Patents Nos. 5,597,956 and 5,405,363, the entire disclosures of which are herein incorporated by reference.

Different subcutaneous electrodes 13 of the present invention are illustrated in FIGS. 1-3. Turning to FIG. 1, the lead 21 for the subcutaneous electrode is preferably composed of silicone or polyurethane insulation. The electrode is connected to the canister at its proximal end via connection port 19 which is located on an electrically insulated area 14 of the canister. The electrode illustrated is a composite electrode with three different electrodes attached to the lead. In the embodiment illustrated, an optional anchor segment 52 is attached at the most distal end of the subcutaneous electrode for anchoring the electrode into soft tissue such that the electrode does not dislodge after implantation.

The most distal electrode on the composite subcutaneous electrode is a coil electrode 27 that is sued for delivering the high voltage cardioversion/ defibrillation energy across the heart. The coil cardioversion/defibrillation electrode is about 5-10 cm in length. Proximal to the coil electrode are two sense electrodes, a first sense electrode 25 is located proximally to the coil electrode and a second sense electrode 23 is located proximally to the first sense electrode. The sense electrodes are spaced far enough apart to be able to have good QRS detection. This spacing can range from 1 to 10 cm with 4 cm being presently preferred. The electrodes may or may not be circumferential with the preferred embodiment. Having the electrodes non-circumferential and positioned outward, toward the skin surface, is a means to minimize muscle artifact and enhance QRS signal quality. The sensing electrodes are electrically isolated from the cardioversion/defibrillation electrode via insulating areas 29. Similar types of cardioversion/defibrillation electrodes are currently commercially available in a transvenous configuration. For example, U.S. Patent No. 5,534,022, the entire disclosure of which is herein incorporated by reference, disclosures a composite electrode with a coil cardioversion/defibrillation electrode and sense electrodes. Modifications to this arrangement are contemplated within the scope of the invention. One such modification is illustrated in FIG. 2 where the two sensing electrodes 25 and 23 are non-circumferential sensing electrodes and one is located at the distal end, the other is located proximal thereto with the coil electrode located in between the two sensing electrodes. In this embodiment the sense electrodes are spaced about 6 to about 12 cm apart depending on the length of

the coil electrode used. FIG. 3 illustrates yet a further embodiment where the two sensing electrodes are located at the distal end to the composite electrode with the coil electrode located proximally thereto. Other possibilities exist and are contemplated within the present invention. For example, having only one sensing electrode, either proximal or distal to the coil cardioversion/ defibrillation electrode with the coil serving as both a sensing electrode and a cardioversion/defibrillation electrode.

It is also contemplated within the scope of the invention that the sensing of QRS waves (and transthoracic impedance) can be carried out via sense electrodes on the canister housing or in combination with the cardioversion/defibrillation coil electrode and/or the subcutaneous lead sensing electrode(s). In this way, sensing could be performed via the one coil electrode located on the subcutaneous electrode and the active surface on the canister housing. Another possibility would be to have only one sense electrode located on the subcutaneous electrode and the sensing would be performed by that one electrode and either the coil electrode on the subcutaneous electrode or by the active surface of the canister. The use of sensing electrodes on the canister would eliminate the need for sensing electrodes on the subcutaneous electrode. It is also contemplated that the subcutaneous electrode would be provided with at least one sense electrode, the canister with at least one sense electrode, and if multiple sense electrodes are used on either the subcutaneous electrode and/or the canister, that the best QRS wave detection combination will be identified when the S-ICD is implanted and this combination can be selected, activating the best sensing arrangement from all the existing sensing possibilities. Turning again to FIG. 2, two sensing electrodes 26 and 28 are located on the electrically active surface 15 with electrical insulator rings 30 placed between the sense electrodes and the active surface. These canister sense electrodes could be switched off and electrically insulated during and shortly after defibrillation/ cardioversion shock delivery. The canister sense electrodes may also be placed on the electrically inactive surface of the canister. In the embodiment of FIG. 2, there are actually four sensing electrodes, two on the subcutaneous lead and two on the canister. In the preferred embodiment, the ability to change which electrodes are used for sensing would be a programmable feature of the S-ICD to adapt to changes in the patient

physiology and size (in the case of children) over time. The programming could be done via the use of physical switches on the canister, or as presently preferred, via the use of a programming wand or via a wireless connection to program the circuitry within the canister.

The canister could be employed as either a cathode or an anode of the S-ICD cardioversion/defibrillation system. If the canister is the cathode, then the subcutaneous coil electrode would be the anode. Likewise, if the canister is the anode, then the subcutaneous electrode would be the cathode.

The active canister housing will provide energy and voltage intermediate to that available with ICDs and most AEDs. The typical maximum voltage necessary for ICDs using most biphasic waveforms is approximately 750 Volts with an associated maximum energy of approximately 40 Joules. The typical maximum voltage necessary for AEDs is approximately 2000-5000 Volts with an associated maximum energy of approximately 200-360 Joules depending upon the model and waveform used. The S-ICD of the present invention uses maximum voltages in the range of about 800 to about 2000 Volts and is associated with energies of about 40 to about 150 Joules. The capacitance of the S-ICD could range from about 50 to about 200 micro farads.

The sense circuitry contained within the canister is highly sensitive and specific for the presence or absence of life threatening ventricular arrhythmias. Features of the detection algorithm are programmable and the algorithm is focused on the detection of V-FIB and high rate V-TACH (>240 bpm). Although the S-ICD of the present invention may rarely be used for an actual life threatening event, the simplicity of design and implementation allows it to be employed in large populations of patients at modest risk with modest cost by non-cardiac electrophysiologists. Consequently, the S-ICD of the present invention focuses mostly on the detection and therapy of the most malignant rhythm disorders. As part of the detection algorithm's applicability to children, the upper rate range is programmable upward for use in children, known to have rapid supraventricular tachycardias and more rapid ventricular fibrillation. Energy levels also are programmable downward in order to allow treatment of neonates and infants.

Turning now to FIG. 4, the optimal subcutaneous placement of the S-ICD of the present invention is illustrated. As would be evident to a person skilled in the art, the actual location of the S-ICD is in a subcutaneous space that is developed during the implantation process. The heart is not exposed during this process and the heart is schematically illustrated in the figures only for help in understanding where the canister and coil electrode are three dimensionally located in the thorax of the patient. The S-ICO canister with the active housing is located in the left mid-clavicular line approximately at the level of the inframammary crease at approximately the 5th rib. The lead 21 of the subcutaneous electrode traverses in a subcutaneous path around the thorax terminating with its distal electrode end at the posterior axillary line ideally just lateral to the left scapula. This way the canister and subcutaneous cardioversion/defibrillation electrode provide a reasonably good pathway for current delivery to the majority of the ventricular myocardium.

FIG. 5 illustrates a different placement of the present invention. The S-ICD canister with the active housing is located in the left posterior axillary line approximately lateral to the tip of the inferior portion of the scapula. This location is especially useful in children. The lead 21 of the subcutaneous electrode traverses in a subcutaneous path around the thorax terminating with its distal electrode end at the anterior precordial region, ideally in the inframammary crease. FIG. 6 illustrates the embodiment of FIG. 1 subcutaneously implanted in the thorax with the proximal sense electrodes 23 and 25 located at approximately the left axillary line with the cardioversion/defibrillation electrode just lateral to the tip of the inferior portion of the scapula.

FIG. 7 schematically illustrates the method for implanting the S-ICD of the present invention. An incision 31 is made in the left anterior axillary line approximately at the level of the cardiac apex. This incision location is distinct from that chosen for S-ICD placement and is selected specifically to allow both canister location more medially in the left inframammary crease and lead positioning more posteriorly via the introducer set (described below) around to the left posterior axillary line lateral to the left scapula. That said, the incision can be anywhere on the thorax deemed reasonably by the implanting physician although in the preferred embodiment, the S-ICD of the present invention will

be applied in this region. A subcutaneous pathway 33 is then created medially to the inframmary crease for the canister and posteriorly to the left posterior axillary line lateral to the left scapula for the lead.

The S-ICD canister 11 is then placed subcutaneously at the location of the incision or medially at the subcutaneous region at the left inframmary crease. The subcutaneous electrode 13 is placed with a specially designed curved introducer set 40 (see FIG. 8). The introducer set comprises a curved trocar 42 and a stiff curved peel away sheath 44. The peel away sheath is curved to allow for placement around the rib cage of the patient in the subcutaneous space created by the trocar. The sheath has to be stiff enough to allow for the placement of the electrodes without the sheath collapsing or bending. Preferably the sheath is made out of a biocompatible plastic material and is perforated along its axial length to allow for it to split apart into two sections. The trocar has a proximal handle 41 and a curved shaft 43. The distal end 45 of the trocar is tapered to allow for dissection of the subcutaneous pathway 33 in the patient. Preferably, the trocar is cannulated having a central Lumen 46 and terminating in an opening 48 at the distal end. Local anesthetic such as lidocaine can be delivered, if necessary, through the lumen or through a curved and elongated needle designed to anesthetize the path to be used for trocar insertion should general anesthesia not be employed. The curved peel away sheath 44 has a proximal pull tab 49 for breaking the sheath into two halves along its axial shaft 47. The sheath is placed over a guidewire inserted through the trocar after the subcutaneous path has been created. The subcutaneous pathway is then developed until it terminates subcutaneously at a location that, if a straight line were drawn from the canister location to the path termination point the line would intersect a substantial portion of the left ventricular mass of the patient. The guidewire is then removed leaving the peel away sheath. The subcutaneous lead system is then inserted through the sheath until it is in the proper location. Once the subcutaneous lead system is in the proper location, the sheath is split in half using the pull tab 49 and removed. If more than one subcutaneous electrode is being used, a new curved peel away sheath can be used for each subcutaneous electrode.

The S-ICD will have prophylactic use in adults where chronic transvenous/epicardial ICD lead systems pose excessive risk or have already resulted in

difficulty, such as sepsis or lead fractures. It is also contemplated that a major use of the S-ICD system of the present invention will be for prophylactic use in children who are at risk for having fatal arrhythmias, where chronic transvenous lead systems pose significant management problems. Additionally, with the use of standard transvenous ICDs in children, problems develop during patient growth in that the lead system does not accommodate the growth. FIG. 9 illustrates the placement of the S-ICD subcutaneous lead system such that the problem that growth presents to the lead system is overcome. The distal end of the subcutaneous electrode is placed in the same location as described above providing a good location for the coil cardioversion/defibrillation electrode 27 and the sensing electrodes 23 and 25. The insulated lead 21, however is no longer placed in a taught configuration. Instead, the lead is serpiginously placed with a specially designed introducer trocar and sheath such that it has numerous waves or bends. As the child grows, the waves or bends will straighten out lengthening the lead system while maintaining proper electrode placement. Although it is expected that fibrous scarring especially around the defibrillation coil will help anchor it into position to maintain its posterior position during growth, a lead system with a distal tine or screw electrode anchoring system 52 can also be incorporated into the distal tip of the lead to facilitate lead stability (see FIG. 1). Other anchoring systems can also be used such as hooks, sutures, or the like.

FIGS. 10 and 11 illustrate another embodiment of the present S-ICD invention. In this embodiment there are two subcutaneous electrodes 13 and 13' of opposite polarity to the canister. The additional subcutaneous electrode 13' is essentially identical to the previously described electrode. In this embodiment the cardioversion/defibrillation energy is delivered between the active surface of the canister and the two coil electrodes 27 and 27'. Additionally, provided in the canister is means for selecting the optimum sensing arrangement between the four sense electrodes 23, 23', 25, and 25'. The two electrodes are subcutaneously placed on the same side of the heart. As illustrated in FIG. 6, one subcutaneous electrode 13 is placed inferiorly and the other electrode 13' is placed superiorly. It is also contemplated with this dual subcutaneous electrode system that the

canister and one subcutaneous electrode are the same polarity and the other subcutaneous electrode is the opposite polarity.

Turning now to FIGS. 12 and 13, further embodiments are illustrated where the canister 11 of the S-ICD of the present invention is shaped to be particularly useful in placing subcutaneously adjacent and parallel to a rib of a patient. The canister is long, thin, and curved to conform to the shape of the patient's rib. In the embodiment illustrated in FIG. 12, the canister has a diameter ranging from about 0.5 cm to about 2 cm with about 1 cm being presently preferred. Alternatively, instead of having a circular cross sectional area, the canister could have a rectangular or square cross sectional area as illustrated in FIG. 13 without falling outside of the scope of the present invention. The length of the canister can vary depending on the size of the patient's thorax. Currently the canister is about 5 cm to about 15 cm long with about 10 cm being presently preferred. The canister is curved to conform to the curvature of the ribs of the thorax. The radius of the curvature will vary depending on the size of the patient, with smaller radiuses for smaller patients and larger radiuses for larger patients. The radius of the curvature can range from about 5 cm to about 25 cm depending on the size of the patient. Additionally, the radius of the curvature need not be uniform throughout the canister such that it can be shaped closer to the shape of the ribs. The canister has an active surface, 15 that is located on the interior (concave) portion of the curvature and an inactive surface 16 that is located on the exterior (convex) portion of the curvature. The leads of these embodiments, which are not illustrated except for the connection port 19 and the proximal end of the lead 21, can be any of the leads previously described above, with the lead illustrated in FIG. 1 being presently preferred.

The circuitry of this canister is similar to the circuitry described above. Additionally, the canister can optionally have at least one sense electrode located on either the active surface of the inactive surface and the circuitry within the canister can be programmable as described above to allow for the selection of the best sense electrodes. It is presently preferred that the canister have two sense electrodes 26 and 28 located on the inactive surface of the canisters as illustrated, where the electrodes are spaced from about

1 to about 10 cm apart with a spacing of about 3 cm being presently preferred. However, the sense electrodes can be located on the active surface as described above.

It is envisioned that the embodiment of FIG. 12 will be subcutaneously implanted adjacent and parallel to the left anterior 5th rib, either between the 4th and 5th ribs or between the 5th and 6th ribs. However other locations can be used.

Another component of the S-ICD of the present invention is a cutaneous test electrode system designed to simulate the subcutaneous high voltage shock electrode system as well as the QRS cardiac rhythm detection system. This test electrode system is comprised of a cutaneous patch electrode of similar surface area and impedance to that of the S-ICD canister itself together with a cutaneous strip electrode comprising a defibrillation strip as well as two button electrodes for sensing of the QRS. Several cutaneous strip electrodes are available to allow for testing various bipole spacings to optimize signal detection comparable to the implantable system.

The S-ICD device and method of the present invention may be embodied in other specific forms without departing from the teachings or essential characteristics of the invention. The described embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore to be embraced therein.

WHAT IS CLAIMED IS:

1. A subcutaneous implantable cardioverter-defibrillator compromising:

(a) an electrically active canister that serves as either an anode or a cathode of the cardioverter-defibrillator wherein the canister houses a source of electrical energy, a capacitor, and operational circuitry that senses the presence of potentially fatal heart rhythms;

(b) a subcutaneous electrode that serves as the opposite electrode from the canister (either the anode or the cathode);

(c) a lead system electrically attaching the electrode to the canister;

(d) means for delivering electrical cardioversion-defibrillation energy when the operational circuitry senses a potentially fatal heart rhythm; and

(e) the absence of a transvenous, intracardic, or epicardial electrode.

2. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating voltage is equal to or greater than 800 Volts.

3. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy ranges from about 40 Joules to about 150 Joules.

4. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the subcutaneous electrode is a composite electrode comprising:

(a) a cardioversion-defibrillation electrode;

(b) a first sensing electrode; and

(c) a second sensing electrode electrically insulated and spaced apart from the first sensing electrode.

5. The subcutaneous implantable cardioverter-defibrillator of Claim 4 wherein the first sensing electrode is located at the distal end of the subcutaneous electrode, the

second sensing electrode is located about 1 to about 10 cm proximal to the first sensing electrode, and the cardioversion-defibrillation electrode is located proximal to the second sensing electrode.

6. The subcutaneous implantable cardioverter-defibrillator of Claim 5 wherein the first and second sensing electrodes are spaced apart by about 4 cm.

7. The subcutaneous implantable cardioverter-defibrillator of Claim 4 wherein the first sensing electrode is located at the distal end of the subcutaneous electrode, the cardioversion-defibrillation electrode is located proximal to the first sensing electrode, and the second sensing electrode is located proximal to the cardioversion-defibrillation sensing electrode.

8. The subcutaneous implantable cardioverter-defibrillator of Claim 4 wherein the cardioversion-defibrillation electrode is located at the distal end of the subcutaneous electrode, the first sensing electrode is located proximally to the cardioversion-defibrillation electrode, and the second sensing electrode is located about 1 to about 10 cm proximal to the first sensing electrode.

9. The subcutaneous implantable cardioverter-defibrillator of Claim 8 wherein the first and second sensing electrodes are spaced apart by about 4 cm.

10. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry can also sense the presence of bradycardia rhythm.

11. The subcutaneous implantable cardioverter-defibrillator of Claim 10 further comprising means for delivering cardiac pacing energy when the operational circuitry senses a bradycardia rhythm.

12. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry is programmable.

13. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry can detect tachycardia.

14. The subcutaneous implantable cardioverter-defibrillator of Claim 13 further comprising means for delivering antitachycardia pacing when the operational circuitry senses a tachycardia rhythm.

15. The subcutaneous implantable cardioverter-defibrillator of Claim 13. Wherein the ventricular tachycardia detected is greater than 240 beats per minute.

16. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry can detect atrial tachycardia and atrial fibrillation.

17. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry can induce ventricular tachycardia or ventricular fibrillation.

18. The subcutaneous implantable cardioverter-defibrillator of Claim 17 wherein the ventricular tachycardia or ventricular fibrillation is induced by shocks on the T wave.

19. The subcutaneous implantable cardioverter-defibrillator of Claim 17 wherein the ventricular tachycardia or ventricular fibrillation is induced by low direct current voltage applied during the entire cardiac cycle.

20. The subcutaneous implantable cardioverter-defibrillator of Claim 2 wherein the electrical cardioversion-defibrillating energy ranges from about 800 volts to about 2000 volts.

21. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy is delivered in a biphasic wave form.

22. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the capacitance is about 50 to about 200 micro farads.

23. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the canister is malleable.

24. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the canister is provided with at least one sensing electrode.

25. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the canister is provided with one or more sensing electrodes, the subcutaneous electrode is provided with one or more sensing electrodes, and means for selecting two sensing electrodes from the sensing electrodes located on the canister and the sensing electrode located on the subcutaneous electrode that provide adequate QRS wave detection.

26. The subcutaneous implantable cardioverter-defibrillator of Claim 1 comprising an additional subcutaneous electrode that serves as the opposite electrode from the canister (either the anode or the cathode) and the same polarity as the original subcutaneous electrode.

27. The subcutaneous implantable cardioverter-defibrillator of Claim 1 comprising an additional subcutaneous electrode that serves as the opposite electrode from the original subcutaneous electrode (either the anode or the cathode) and the same polarity as the canister.

28. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy is delivered for about 10 to about 20

milliseconds total duration and with the initial positive phase containing approximately 2/3 of the energy delivered.

29. The subcutaneous implantable cardioverter-defibrillator of Claim 1 further comprising an attachment member located at the distal end of the subcutaneous electrode for attaching the subcutaneous electrode to nearby tissue.

30. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry comprises an impedance detection for measuring the undulations in transthoracic impedance created during respiration.

31. The subcutaneous implantable cardioverter-defibrillator of Claim 30 wherein the operational circuitry can also measure the cardiac output using transthoracic impedance.

32. The subcutaneous implantable cardioverter-defibrillator of Claim 16 wherein the operational circuitry can deliver defibrillation energy to treat the detected atrial fibrillation.

33. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the canister is long, thin, and curved such that it is shaped to be subcutaneously implanted adjacent to and parallel with ribs of a patent.

34. A method of implanting a subcutaneous cardioverter-defibrillator in a patient comprising the steps of:

(1) making only one skin incision in the thoracic region of the patient;

(2) inserting a curved introducer through the skin incision to make a subcutaneous path in the thoracic region such that the path terminates subcutaneously at a location that if a straight line were drawn from the skin incision to the path termination the line would intersect the heart of the patient;

(3) implanting an electrode subcutaneously at the path termination point;

(4) placing an electrically active canister subcutaneously at the skin incision point wherein the canister contains a source of electrical energy and operational circuitry that senses the presence of potentially fatal heart rhythms and has means for delivering electrical cardioversion-defibrillation energy using the canister as either the anode or the cathode and using the electrode as the opposite electrode from the canister, and wherein the canister is electrically connected to the electrode; and

(5) closing the skin incision.

35. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 34 further comprising the step of injecting a local anesthetic through the curved introducer.

36. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 34 wherein the skin incision is located in the left anterior axillary line approximately at the level of the patient's cardiac apex.

37. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 36 wherein the electrode is subcutaneously implanted in the left posterior axillary line lateral to the left scapula.

38. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 36 wherein the canister is subcutaneously implanted in the left inframammary crease of the patient.

39. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 34 wherein the skin incision is located in the left posterior axillary line of the patient approximately at a level lateral to the tip of the left scapula of the patient.

40. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 39 wherein the electrode is implanted in the anterior precordial region of the patient.

41. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 40 wherein the electrode is implanted in the inframammary crease of the patient.

42. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 34 wherein the operational circuitry can detect the presence of bradycardia rhythms.

43. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 42 wherein the device has means of delivering electrical cardiac pacing energy when the operational circuitry senses a bradycardia rhythm.

44. A subcutaneous implantable cardioverter-defibrillator kit comprising:

(a) a tray for storing the subcutaneous implantable cardioverter-defibrillator;

(b) an electrically active canister that serves as either an anode or a cathode of the cardioverter-defibrillator wherein the canister houses a source of electrical energy and operational circuitry that senses the presence of potentially fatal heart rhythms stored in the tray;

(c) an electrode that serves as the opposite electrode from the canister (either the anode or the cathode) stored in the tray;

(d) a lead system electrically attaching the electrode to the canister stored in the tray; and

(e) means for delivering electrical cardioversion-defibrillation energy when the operational circuitry senses a potentially fatal heart rhythm stored in the tray.

45. The subcutaneous implantable cardioverter-defibrillator kit of Claim 44 further comprising a curved introducer stored in the tray.

46. The subcutaneous implantable cardioverter-defibrillator kit of Claim 45 further comprising a local anesthetic for injecting through the curved introducer stored in the tray.

47. The subcutaneous implantable cardioverter-defibrillator kit of Claim 45 further comprising a curved rigid peel away sheath stored in the kit.

48. A cardioverter-defibrillator for subcutaneous implantation, comprising:

a canister comprising a biocompatible housing enclosing and containing cardioversion-defibrillation circuitry and defining at least one electrically conductive surface on an outer surface of the biocompatible housing and electrically connected to the cardioversion-defibrillation circuitry;

an electrically inert lead comprising a substantially pliant and directable cannula adaptably connected to the canister; and

a lead electrode formed on a distal end of the electrically inert and electrically interfaced to the cardioversion-defibrillation circuitry to deliver an electrical therapy to the at least one electrically conductive surface.

49. A cardioverter-defibrillator according to Claim 48, further comprising:

at least one sensing electrode formed on and electrically insulated from the at least one electrically conductive surface and electrically interfaced to the cardioversion-defibrillation circuitry.

50. A cardioverter-defibrillator according to Claim 48, further comprising:

at least one electrically insulated surface defined on the outer surface of the biocompatible housing and juxtaposed to the at least one electrically conductive surface.

51. A cardioverter-defibrillator according to Claim 50, further comprising:

at least one sensing electrode formed on the at least one electrically insulated surface and electrically interfaced to the cardioversion-defibrillation circuitry.

52. A cardioverter-defibrillator according to Claim 50, further comprising:

a focused margin bounding the at least one electrically conductive surface from the at least one electrically insulated surface and defining a concentrated electrically conductive surface within the at least one electrically insulated surface.

53. A cardioverter-defibrillator according to Claim 50, wherein the at least one electrically insulated surface is constructed from at least one of a silicon, polyurethane, ceramic, titanium-ceramic bonded, Parylene-coated, and similarly characteristic biocompatible material.

54. A cardioverter-defibrillator according to Claim 48, further comprising:

monitoring circuitry integral to the cardioversion-defibrillation circuitry and deriving physiological measures relating to at least one of QRS signal morphology, QRS signal frequency content, QRS R-R interval stability data, and QRS amplitude characteristics.

55. A cardioverter-defibrillator according to Claim 48, further comprising:

a pulse generator integral to the cardioversion-defibrillation circuitry and producing an anti-arrhythmia waveform for anti-arrhythmia therapy via the at least one electrically conductive surface and the lead electrode responsive to the cardioversion-defibrillation circuitry.

56. A cardioverter-defibrillator according to Claim 55, further comprising:

the pulse generator generating the anti-arrhythmia waveform as a biphasic waveform with characteristics comprising at least one of a capacitance between approximately 50 μF and 200 μF, voltage between approximately 800 V and 2000 V, energy between 40 J and 150 J, and a duration between approximately 5 msec to 25 msec.

57. A cardioverter-defibrillator according to Claim 56, further comprising:

the cardioversion-defibrillation circuitry initiating the anti-arrhythmia therapy upon a cardiac ventricular rate of around 240 bpm sustained over an at least 4 second interval.

58. A cardioverter-defibrillator according to Claim 56, further comprising:

the cardioversion-defibrillation circuitry confirming the anti-arrhythmia therapy upon a cardiac ventricular rate of around 240 bpm sustained over an approximately 1 second interval.

59. A cardioverter-defibrillator according to Claim 56, further comprising:

the cardioversion-defibrillation circuitry terminating the anti-arrhythmia therapy upon a cardiac ventricular rate of around 240 bpm sustained over an at least 4 second interval.

60. A cardioverter-defibrillator according to Claim 56, further comprising:

power supply components integral to the cardioversion-defibrillation circuitry, consisting essentially of four or more batteries and four or more capacitors and providing power sufficient to generate the anti-arrhythmia waveform.

61. A cardioverter-defibrillator according to Claim 48, further comprising:

pacing circuitry operatively conjunctive to the cardioversion-defibrillation circuitry which generates at least one of an anti-bradycardia and an anti-tachycardia pacing waveform via the at least one electrically conductive surface and the lead electrode responsive to the cardioversion-defibrillation circuitry.

62. A cardioverter-defibrillator according to Claim 48, further comprising:

induction circuitry integral to the cardioversion-defibrillation circuitry which generates low amplitude voltage on a T-wave of an ECG via the at least one electrically conductive surface and the lead electrode responsive to the cardioversion-defibrillation circuitry.

63. A cardioverter-defibrillator according to Claim 48, further comprising:

a downward taper continuously formed along an exterior periphery of the biocompatible housing terminating substantially at a surface opposite a connection port to the electrically inert lead.

64. A cardioverter-defibrillator according to Claim 63, further comprising:

a pair of semi-converging tapers continuously formed about opposite sides of the downward taper and terminating substantially at the surface opposite the connection port to the electrically inert lead.

65. A cardioverter-defibrillator according to Claim 48, further comprising:

a radian bend continuously formed approximately axial to the biocompatible housing.

66. A cardioverter-defibrillator according to Claim 65, further comprising:

a cross-section defined approximately transverse to the biocompatible housing and comprising at least one of a square and rectangular shapes.

67. A cardioverter-defibrillator according to Claim 48, further comprising:

at least one of a fractalized and a wrinkled surface formed on the outer surface of the biocompatible housing.

68. A cardioverter-defibrillator according to Claim 48, further comprising:

biocompatible housing is constructed from at least one of a titanium alloy and similarly characteristic biocompatible material, such material being malleable.

69. A cardioverter-defibrillator according to Claim 48, further comprising:

monitoring circuitry integral to the cardioversion-defibrillation circuitry and obtaining physiological measures via at least one of the lead electrode and the at least one electrically conductive surface.

70. A cardioverter-defibrillator according to Claim 48, further comprising:

the lead electrode formed non-circumferentially on the electrically inert lead and with an overall length of an electrically active component of less than approximately 10 cm.

71. A cardioverter-defibrillator according to Claim 48, further comprising:

the lead electrode interfacing with high voltage and low impedance circuitry.

72. A cardioverter-defibrillator according to Claim 71, further comprising:

a plurality of sensing electrodes formed on the electrically inert lead, each sensing electrode interfacing with low voltage and high impedance circuitry.

73. A cardioverter-defibrillator according to Claim 72, further comprising:

each such sensing electrode formed distal to the lead electrode.

74. A cardioverter-defibrillator according to Claim 72, further comprising:

each such sensing electrode formed proximal to the lead electrode.

75. A cardioverter-defibrillator according to Claim 72, further comprising:

at least one such sensing electrode formed distal to the lead electrode and at least one such sensing electrode formed proximal to the lead electrode.

76. A cardioverter-defibrillator according to Claim 72, further comprising:

at least one such sensing electrode formed non-circumferentially on the electrically inert lead.

77. A cardioverter-defibrillator according to Claim 48, further comprising:

at least one further electrically inert lead comprising a substantially pliant and directable cannula connected on the proximal end to the canister;

at least one further lead electrode formed on a distal end of the at least one further electrically inert lead and electrically interfaced to the cardioversion-defibrillation circuitry; and

switching circuitry to selectively deliver an electrical therapy between the at least one electrically conductive surface and one or more of the lead electrodes on the electrically inert leads.

78. A cardioverter-defibrillator according to Claim 48, further comprising:

a plurality of pliant bends formed in the electrically inert lead to form a serpiginous lead implantation.

79. A cardioverter-defibrillator according to Claim 48, further comprising:

an anchor segment fixedly attached to the distal end of the electrically inert lead to form a secured lead implantation.

80. A cardioverter-defibrillator according to Claim 48, wherein the electrically inert lead is constructed from at least one of a silicon, polyurethane, ceramic, and similarly characteristic biocompatible material.

81. A subcutaneous cardioverter-defibrillator with electrically active canister for minimally invasive implantation, comprising:

a subcutaneously implantable canister comprising a sterilizable biocompatible housing enclosing and containing cardioversion-defibrillation circuitry interfaceable through the biocompatible housing via an electrically isolated connector block, the biocompatible housing defining at least one electrically conductive surface on the outer surface of the biocompatible housing and electrically connected to the cardioversion-defibrillation circuitry;

an electrically inert lead comprising a substantially pliant and directable cannula enclosing and guiding one or more conductors adaptably connected to the electrically isolated connector block; and

a lead electrode formed on a distal end of the electrically inert lead and electrically interfaced via the one or more conductors to the cardioversion-defibrillation circuitry to deliver an electrical therapy to the at least one electrically conductive surface.

82. A subcutaneous cardioverter-defibrillator according to Claim 81, further comprising:

the lead electrode further interfacing with sensing circuitry and providing a sensing function to the cardioversion-defibrillation circuitry.

83. A subcutaneous cardioverter-defibrillator according to Claim 81, further comprising:

a concentrated electrically conducive surface defined about a surface of the biocompatible housing facing the heart.

84. A subcutaneous cardioverter-defibrillator according to Claim 81, further comprising:

at least one electrically insulated surface defined about a surface of the biocompatible housing facing away from the heart and juxtaposed to the at least one electrically conductive surface.

85. A subcutaneous cardioverter-defibrillator according to Claim 84, further comprising:

an insulating area substantially interposed between the at least one electrically conductive surface and at the at least one electrically insulated surface.

86. A subcutaneous cardioverter-defibrillator according to Claim 81, further comprising:

at least one sensing electrode formed on and electrically insulated from the at least one electrically conductive surface and electrically interfaced to the cardioversion-defibrillation circuitry, each sensing electrode interfacing with sensing circuitry and providing a sensing function to the cardioversion-defibrillation circuitry.

87. A subcutaneous cardioverter-defibrillator according to Claim 86, further comprising:

an electrically insulated surface about each at least one sensing electrode abutting the biocompatible housing and marginal to the at least one electrically conductive surface.

88. A subcutaneous cardioverter-defibrillator according to Claim 81, further comprising:

a plurality of sensing electrodes formed on the electrically inert lead and electrically interfaced via the one or more conductors to the cardioversion-defibrillation circuitry, each sensing electrode interfacing with sensing circuitry and providing a sensing function to the cardioversion-defibrillation circuitry.

89. A subcutaneous cardioverter-defibrillator according to Claim 88, further comprising:

each of the sensing electrodes formed in locations comprising at least one of a location distal to the lead electrode, proximal to the lead electrode, and in juxtaposition to the lead electrode.

90. A subcutaneous cardioverter-defibrillator according to Claim 88, further comprising:

at least one such sensing electrode formed non-circumferentially along an interior surface of the electrically inert lead.

91. A subcutaneous cardioverter-defibrillator according to Claim 81, further comprising:

a downward taper continuously formed along an exterior periphery of the biocompatible housing terminating substantially at a surface opposite the connector block; and

a pair of semi-converging tapers continuously formed about opposite sides of the downward taper and terminating substantially at the surface opposite the connector block.

92. A subcutaneous cardioverter-defibrillator according to Claim 81, further comprising:

a radian bend continuously formed approximately axial to the biocompatible housing.

93. A subcutaneous cardioverter-defibrillator according to Claim 81, further comprising:

at least one further electrically inert lead comprising a substantially pliant and directable cannula enclosing and guiding one or more conductors adaptably connected to the electrically isolated connector block;

at least one further lead electrode formed on a distal end of the at least one further electrically inert lead and electrically interfaced via the one or more conductors to the cardioversion-defibrillation circuitry to deliver an electrical therapy to the at least one electrically conductive surface; and

switching circuitry controllable via the cardioversion-defibrillation circuitry to selectively deliver an electrical therapy between the at least one electrically conductive surface and one or more of the lead electrodes on the electrically inert leads.

94. A subcutaneous cardioverter-defibrillator according to Claim 81, further comprising:

an anchor segment comprising an electrically inert anchoring device fixedly attached to the distal end of the electrically inert lead to form a secured lead implantation within soft tissue.

95. A subcutaneous cardioverter-defibrillator according to Claim 81, further comprising:

a pulse generator integral to the cardioversion-defibrillation circuitry and generating an anti-arrhythmia biphasic waveform with characteristics comprising at least one of a capacitance between approximately 50 μF and 200 μF, voltage between approximately 800 V and 2000 V, energy between 40 J and 150 J, and a duration between approximately 5 msec to 25 msec.

96. A subcutaneous cardioverter-defibrillator according to Claim 94, further comprising:

self-contained power supply components contained within the biocompatible housing and integral to the cardioversion-defibrillation circuitry, consisting essentially of four or more batteries and four or more capacitors and providing power sufficient to generate the anti-arrhythmia biphasic waveform.

97. A subcutaneous cardioverter-defibrillator according to Claim 81, further providing:

the cardioversion-defibrillation circuitry comprising at least one of:

monitoring circuitry deriving physiological measures relating to at least one of QRS signal morphology, QRS signal frequency content, QRS R-R interval stability data, and QRS amplitude characteristics;

a pulse generator producing an anti-arrhythmia waveform for anti-arrhythmia therapy via the at least one electrically conductive surface and the lead electrode responsive to the cardioversion-defibrillation circuitry;

pacing circuitry operatively conjunctive to the cardioversion-defibrillation circuitry which generates at least one of an anti-bradycardia and an anti-tachycardia pacing waveform via the at least one electrically conductive surface and the lead electrode responsive to the cardioversion-defibrillation circuitry; and

induction circuitry generating low amplitude voltage on a T-wave of an ECG via the at least one electrically conductive surface and the lead electrode responsive to the cardioversion-defibrillation circuitry.

98. A subcutaneous cardioverter-defibrillator according to Claim 81, wherein the biocompatible housing is constructed from at least one of a titanium alloy and similarly characteristic biocompatible material, such material being malleable, and the electrically inert lead is constructed from at least one of a silicon, polyurethane, ceramic, and similarly characteristic biocompatible material.

99. A cardioversion-defibrillation device with electrically conductive housing means for subcutaneous implantation, comprising:

means for housing and hermetically containing cardioversion-defibrillation circuitry, the housing means comprising electrically isolated means for externally interfacing to the cardioversion-defibrillation circuitry and defining at least one electrically conductive surface on an outer surface of the housing means that is electrically connected to the cardioversion-defibrillation circuitry through internal interfacing means;

means for guiding and enclosing one or more conductors connected to the cardioversion-defibrillation circuitry via the external interfacing means, the enclosing means being substantially pliant and directable; and

means for delivering an electrical therapy from a distal end of the guiding means to the at least one electrically conductive surface response to an autonomously detected arrhythmic condition, the electrical therapy delivering means being electrically connected via the one or more conductors to the cardioversion-defibrillation circuitry.

100. A cardioversion-defibrillation device according to Claim 99, further comprising:

means for monitoring and deriving physiological measures relating to at least one of QRS signal morphology, QRS signal frequency content, QRS R-R interval stability data, and QRS amplitude characteristics;

means for producing an anti-arrhythmia waveform for anti-arrhythmia therapy via the at least one electrically conductive surface and the electrical therapy delivering means responsive to the cardioversion-defibrillation circuitry;

101. A cardioversion-defibrillation device according to Claim 99, further comprising:

sensing means provided via the electrical therapy delivering means, the sensing means being electrically connected via the one or more conductors to the cardioversion-defibrillation circuitry to interface with sensing circuitry.

102. A cardioversion-defibrillation device according to Claim 99, further comprising:

sensing means provided abutting and electrically insulated from the housing means, the sensing means being electrically connected via the internal interfacing means to the cardioversion-defibrillation circuitry to interface with sensing circuitry.

103. A cardioversion-defibrillation device according to Claim 99, further comprising:

sensing means provided on the guiding means adjunctively to the electrical therapy delivering means, the sensing means being electrically connected via the one or more conductors to the cardioversion-defibrillation circuitry to interface with sensing circuitry.

104. A subcutaneous cardioverter-defibrillator according to Claim 96, further comprising:

each of the sensing means formed in locations comprising at least one of a location distal to the electrical therapy delivering means, proximal to the electrical therapy delivering means, and in juxtaposition to the electrical therapy delivering means.

105. A cardioversion-defibrillation device according to Claim 99, further comprising:

at least one electrically insulated surface defined about a surface of the housing means facing the heart and juxtaposed to the at least one electrically conductive surface, an insulating area being substantially interposed between the at least one electrically conductive surface and the at least one electrically insulated surface.

106. A cardioversion-defibrillation device according to Claim 99, further comprising:

pulse generating means integral to the cardioversion-defibrillation circuitry and generating an anti-arrhythmia biphasic waveform with characteristics comprising at least one of a capacitance between approximately 50 μF and 200 μF, voltage between approximately 800 V and 2000 V, energy between 40 J and 150 J, and a duration between approximately 5 msec to 25 msec.

107. A cardioversion-defibrillation device according to Claim 99, further comprising:

a downward taper continuously formed along an exterior periphery of the housing means terminating substantially at a surface opposite the external interfacing means; and

a pair of semi-converging tapers continuously formed about opposite sides of the downward taper and terminating substantially at the surface opposite the external interfacing means.

108. A cardioversion-defibrillation device according to Claim 99, further comprising:

a radian bend continuously formed approximately axial to the housing means.

109. A cardioversion-defibrillation device according to Claim 99, further comprising:

anchoring means fixedly attached to the distal end of the guiding means to form a secured lead implantation within soft tissue.

110. A cardioversion-defibrillation device according to Claim 99, wherein the housing means is constructed from at least one of a titanium alloy and similarly characteristic biocompatible material, such material being malleable, and the guiding means is constructed from at least one of a silicon, polyurethane, ceramic, and similarly characteristic biocompatible material.

111. An implantable subcutaneous cardioverter-defibrillator with electrically active canister, comprising:

an implantable canister providing a housing enclosing and containing cardioversion-defibrillation circuitry externally interfaceable via an electrically isolated connector block on a proximal end of the housing, the housing defining an electrically conductive surface on an outer surface and internally connecting electrically to the cardioversion-defibrillation circuitry;

a substantially pliant and directable lead enclosing and guiding one or more conductors adaptably connected to the electrically isolated connector block, the lead being electrically inert; and

a lead electrode circumferentially formed on a distal end of the lead and electrically interfaced via the one or more conductors to the cardioversion-defibrillation circuitry to deliver an electrical therapy to the electrically conductive surface response to an autonomously detected arrhythmic condition.

112. An implantable subcutaneous cardioverter-defibrillator according to Claim 111, further comprising:

an electrically insulated surface juxtaposed to the discrete electrically conductive surface and substantially interposed therefrom by an electrically insulated area.

113. An implantable subcutaneous cardioverter-defibrillator according to Claim 111, further comprising:

a plurality of sensing electrodes circumferentially formed on the lead and electrically connected with the one or more conductors via the isolated connector block to the cardioversion-defibrillation circuitry, each of the sensing electrodes interfacing with sensing circuitry within the cardioversion-defibrillation circuitry and providing a sensing function.

114. An implantable subcutaneous cardioverter-defibrillator according to Claim 113, further comprising:

each of the sensing electrodes formed in locations along the lead comprising at least one of contiguous locations distal to the lead electrode, contiguous locations proximal to the lead electrode, and discontinuous locations in juxtaposition to the lead electrode.

115. An implantable subcutaneous cardioverter-defibrillator according to Claim 111, further comprising:

at least one sensing electrode formed on and electrically insulated from the electrically conductive surface and internally electrically connected to the cardioversion-defibrillation circuitry, each sensing electrode interfacing with sensing circuitry within the cardioversion-defibrillation circuitry and providing a sensing function.

116. An implantable subcutaneous cardioverter-defibrillator according to Claim 111, further comprising:

an anti-arrhythmic pulse generator integral to the cardioversion-defibrillation circuitry and generating an anti-arrhythmia biphasic waveform to the electrically conductive surface with characteristics comprising at least one of a capacitance between approximately 50 μF and 200 μF, voltage between approximately 800 V and 2000 V, energy between 40 J and 150 J, and a duration between approximately 5 msec to 25 msec.

117. An implantable subcutaneous cardioverter-defibrillator with discrete electrically active canister, comprising:

an implantable canister providing a housing enclosing and containing cardioversion-defibrillation circuitry externally interfaceable via an electrically isolated connector block on a proximal end of the housing, the housing defining a discrete electrically conductive surface on an outer surface and internally connecting electrically to the cardioversion-defibrillation circuitry, the housing further defining an electrically insulated surface juxtaposed to the discrete electrically conductive surface and substantially interposed therefrom by an electrically insulated area;

a substantially pliant and directable lead enclosing and guiding one or more conductors adaptably connected to the electrically isolated connector block, the lead being electrically inert; and

a lead electrode circumferentially formed on a distal end of the lead and electrically interfaced via the one or more conductors to the cardioversion-defibrillation circuitry to deliver an electrical therapy to the discrete electrically conductive surface response to an autonomously detected arrhythmic condition.

118. An implantable subcutaneous cardioverter-defibrillator according to Claim 117, further comprising:

at least one sensing electrode formed on at least one of the discrete electrically conductive surface and the electrically insulated surface, the at least one sensing electrode being electrically insulated from the discrete electrically conductive surface and internally electrically connected to the cardioversion-defibrillation circuitry, each sensing electrode interfacing with sensing circuitry within the cardioversion-defibrillation circuitry and providing a sensing function.

119. An implantable subcutaneous cardioverter-defibrillator providing anti-arrhythmia therapy, comprising:

an implantable canister providing a housing enclosing and containing cardioversion-defibrillation circuitry externally interfaceable via an electrically isolated connector block on a proximal end of the housing, the housing defining an electrically conductive surface on an outer surface and internally connecting electrically to the cardioversion-defibrillation circuitry, the cardioversion-defibrillation circuitry monitoring cardiac physiological conditions;

a substantially plaint and directable lead enclosing and guiding one or more conductors adaptably connected to the electrically isolated connector block, the lead being electrically inert; and

a lead electrode circumferentially formed on a distal end of the lead and electrically interfaced via the one or more conductors to the cardioversion-defibrillation circuitry to deliver an anti-arrhythmic waveform to the electrically conductive surface response to an arrhythmic condition autonomously detected by the cardioversion-defibrillation circuitry.

120. An implantable subcutaneous cardioverter-defibrillator according to Claim 119, wherein the anti-arrhythmia biphasic waveform has characteristics comprising at least one of capacitance between approximately 50 μF and 200 μF, voltage between

approximately 800 V and 2000 V, energy between 40 J and 150 J, and a duration between approximately 5 msec to 25 msce.

121. An implantable subcutaneous cardioverter-defibrillator monitoring cardiac physiological conditions, comprising:

an implantable canister providing a housing enclosing and containing cardioversion-defibrillation circuitry externally interfaceable via an electrically isolated connector block on a proximal end of the housing, the housing defining an electrically conductive surface on an outer surface and internally connecting electrically to the cardioversion-defibrillation circuitry;

a substantially pliant and directable lead enclosing and guiding one or more conductors adaptably connected to the electrically isolated connector block, the lead being electrically inert;

a sensing electrode circumferentially formed on a distal end of the lead and electrically interfaced via the one or more conductors to sensing circuitry within the cardioversion-defibrillation circuitry to deliver an electrical therapy to the electrically conductive surface response to an autonomously detected arrhythmic condition; and

monitoring circuitry integral to the cardioversion-defibrillation circuitry and deriving cardiac physiological measures relating to at least one of QRS signal morphology, QRS signal frequency content, QRS R-R interval stability data, and QRS amplitude characteristics.

122. an implantable subcutaneous cardioverter-defibrillator providing cardiac pacing, comprising:

an implantable canister providing a housing enclosing and containing cardioversion-defibrillation circuitry externally interfaceable via an electrically isolated connector block on a proximal end of the housing, the housing defining an electrically conductive surface on an outer surface and internally connecting electrically to the cardioversion-defibrillation circuitry;

a substantially pliant and directable lead enclosing and guiding one or more conductors adaptably connected to the electrically isolated connector block, the lead being electrically inert; and

a lead electrode circumferentially formed on a distal end of the lead and electrically interfaced via the one or more conductors to the cardioversion-defibrillation circuitry to deliver an electrical therapy to the electrically conductive surface responsive to an autonomously detected arrhythmic condition; and

pacing circuitry operatively conjunctive to the cardioversion-defibrillation circuitry which generates at least one of an anti-bradycardia and an anti-tachycardia pacing waveform via the electrically conductive surface and the lead electrode responsive to the cardioversion-defibrillation circuitry.

123. An implantable subcutaneous cardioverter-defibrillator inducing cardiac fibrillating episodes, comprising:

an implantable canister providing a housing enclosing and containing cardioversion-defibrillation circuitry externally interfaceable via an electrically isolated connector block on a proximal end of the housing, the housing defining an electrically conductive surface on an outer surface and internally connecting electrically to the cardioversion-defibrillation circuitry;

a substantially pliant and directable lead enclosing and guiding one or more conductors adaptably connected to the electrically isolated connector block, the lead being electrically inert;

a lead electrode circumferentially formed on a distal end of the lead and electrically interfaced via the one or more conductors to the cardioversion-defibrillation circuitry to deliver an electrical therapy to the electrically conductive surface responsive to an autonomously detected arrhythmic condition; and

induction circuitry integral to the cardioversion-defibrillation circuitry which generates low amplitude voltage on a T-wave of an ECG via the electrically conductive surface and the lead electrode responsive to the cardioversion-defibrillation circuitry.

124. An implantable subcutaneous cardioverter-defibrillator detecting cardiopulmonary physiological conditions, comprising:

an implantable canister providing a housing enclosing and containing cardioversion-defibrillation circuitry externally interfaceable via an electrically isolated connector block on a proximal end of the housing, the housing defining an electrically conductive surface on an outer surface and internally connecting electrically to the cardioversion-defibrillation circuitry;

a substantially plaint and directable lead enclosing and guiding one or more conductors adaptably connected to the electrically isolated connector block, the lead being electrically inert; and

a sensing electrode circumferentially formed on a distal end of the lead and electrically interfaced via the one or more conductors to sensing circuitry within the cardioversion-defibrillation circuitry to deliver an electrical therapy to the electrically conductive surface response to an autonomously detected arrhythmic condition; and

detection circuitry integral to the cardioversion-defibrillation circuitry and deriving physiological measures relating to at least one of atrial fibrillation, ventricular fibrillation, transthoracic impedance, respiratory rate, heart rate, cardiac output, ECG shape and temperature.

125. A method for providing anti-arrhythmia therapy via a subcutaneous cardioverter-defibrillator, comprising:

implanting a canister comprising a biocompatible housing subcutaneously in a patient in the anterior thorax approximately level with the inframammary crease, the biocompatible housing enclosing and containing cardioversion-defibrillation circuitry and defining at least one electrically conductive surface on an outer surface of the biocompatible housing and electrically connected to the cardioversion-defibrillation circuitry;

implanting an electrically inert lead subcutaneously in the posterolateral thorax extending circumferentially around the thorax to a position approximately lateral to the tip of the left inferior portion of the scapula, the electrically inert lead comprising a

substantially pliant and directable cannula adaptably connected to the canister with a lead electrode formed on a distal end of the electrically inert lead and electrically interfaced to the cardioversion-defibrillation circuitry; and

delivering an electrical therapy comprising an anti-arrhythmia waveform from the lead electrode to the at least one electrically conductive surface.

126. A method according to Claim 125, further comprising:

at least one further electrically inert lead comprising a substantially pliant and directable cannula connected on the proximal end to the canister;

at least one further lead electrode formed on a distal end of the at least one further electrically inert lead and electrically interfaced to the cardioversion-defibrillation circuitry; and

switching circuitry to selectively deliver an electrical therapy between the at least one electrically conductive surface and one or more of the lead electrodes on the electrically inert leads.

127. A method according to Claim 126, further comprising:

fixedly attaching the distal end of one or more of the electrically inert leads to tissue in the left posterolateral thorax to form a secured lead implantation.

128. A method according to Claim 125, wherein the lead electrode interfaces, the method further comprising:

providing a plurality of sensing electrodes formed on the electrically inert lead, each sensing electrode interfacing with sensing circuitry in the cardioversion-defibrillation circuitry; and

monitoring and deriving cardiac physiological measures relating to at least one of QRS signal morphology, QRS signal frequency content, QRS R-R interval stability data, and QRS amplitude characteristics via the sensing electrodes.

129. A method according to Claim 125, further comprising:

fixedly attaching the distal end of the at least one electrically inert lead to tissue in the left posterolateral thorax to form a secured lead implantation.

130. A method according to Claim 125, further comprising:

implanting a plurality of pliant bends formed in the electrically inert lead subcutaneously in the thorax transverse to the inframammary crease to form a serpiginous lead implantation.

131. A method according to Claim 125, further comprising:

generating low amplitude voltage on a T-wave of an ECG via the at least one electrically conductive surface and the lead electrode responsive to the cardioversion-defibrillation circuitry.

132. A method for providing anti-arrhythmia therapy via a posterolateral implanted subcutaneous cardioverter-defibrillator, comprising:

implanting a canister comprising a biocompatible housing subcutaneously in a patient to a position approximately lateral to the left scapula, the biocompatible housing enclosing and containing cardioversion-defibrillation circuitry and defining at least one electrically conductive surface on an outer surface of the biocompatible housing and electrically connected to the cardioversion-defibrillation circuitry;

implanting an electrically inert lead subcutaneously in the anterior thorax extending around the thorax approximately level with the inframammary crease, the electrically inert lead comprising a substantially pliant and directable cannula adaptably connected to the canister with a lead electrode formed on a distal end of the electrically inert lead and electrically interfaced to the cardioversion-defibrillation circuitry; and

delivering an electrical therapy comprising an anti-arrhythmia waveform from the lead electrode to the at least one electrically conductive surface.

133. A method for simulating anti-arrhythmia therapy as provided by a subcutaneous cardioverter-defibrillator, comprising:

positioning an anterior patch electrode cutaneously on a patient approximately level with the inframammary crease, the patch electrode approximating at least one electrically conductive surface used by a subcutaneous cardioverter-defibrillator;

positioning a strip electrode cutaneously on the patent along a posterolateral thorax location axillary line extending circumferentially around the thorax to a position approximately lateral to the left scapula, the strip electrode approximating a lead electrode electrically interfaced to the subcutaneous cardioverter-defibrillator; and

delivering an electrical therapy comprising an anti-arrhythmia waveform from the strip electrode to the patch electrode.

134. A method according to Claim 132, further comprising:

positioning a plurality of sensing electrodes cutaneously in a location on the patient proximate to at least one of the anterior patch electrode and the strip electrode, the sensing electrodes approximating sensing electrodes interfaced to the subcutaneous cardioverter-defibrillator; and

monitoring and deriving cardiac physiological measures relating to at least one of QRS signal morphology, QRS signal frequency content, QRS R-R interval stability data, and QRS amplitude characteristics via the sensing electrodes.

135. A method according to Claim 85, further comprising:

positioning at least one further strip electrode cutaneously on the posterolateral thorax, each at least one further strip electrode approximating an additional lead electrode electrically interfaced to the subcutaneous cardioverter-defibrillator; and

switching circuitry to selectively deliver a simulated electrical therapy between the patch electrode and one or more of the strip electrodes.

136. An apparatus for implanting a subcutaneous cardioverter-defibrillator, further comprising:

a curved trocar comprising a tubular canulla defining a central lumen along an axial length and affixed to a proximal handle, the tubular canulla having a tapered distal end styled to dissect a subcutaneous path within a patient;

a directable and substantially non-pliant guidewire provided through the central lumen; and

a curved sheath removably fitting over the guidewire and maintaining a subcutaneous pathway during a lead implantation.

137. An apparatus according to Claim 130, further comprising:

a series of axial perforations formed along a length of the sheath enabling longitudinal separation of the sheath.

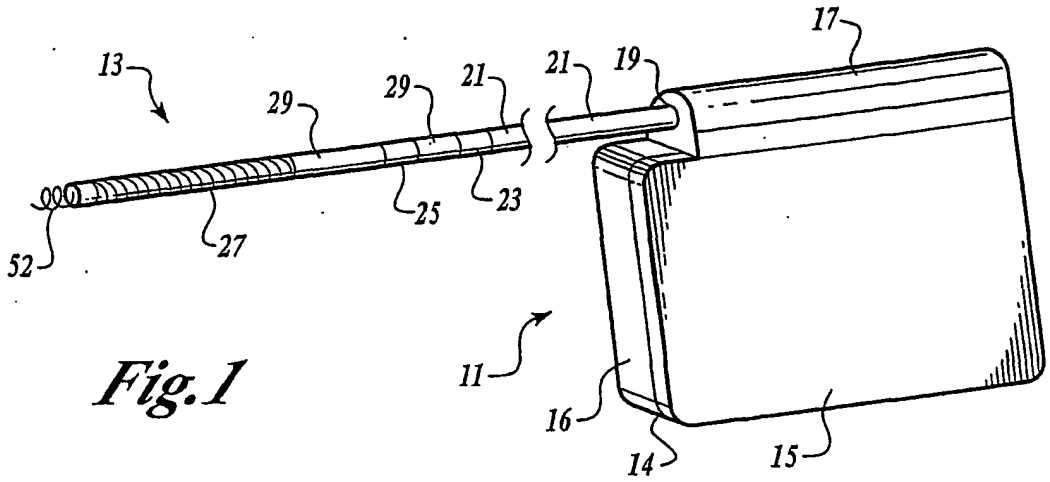


Fig.1

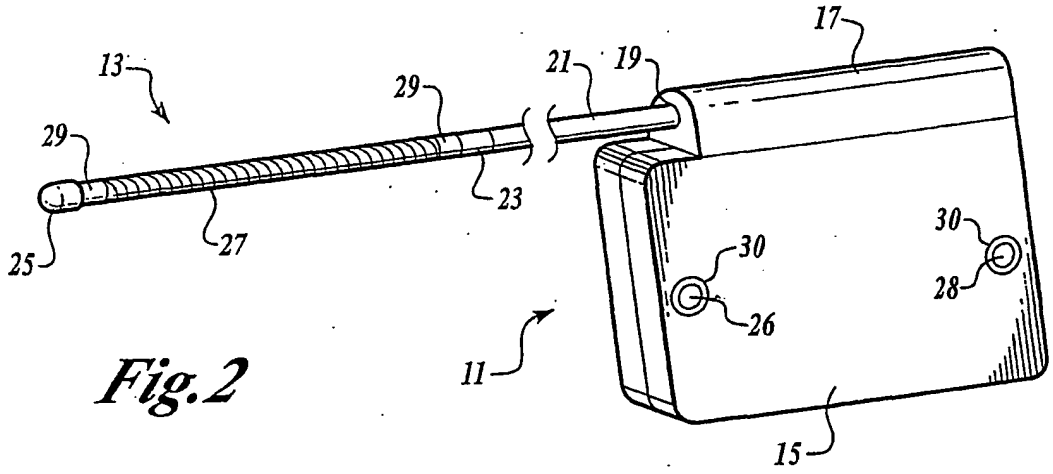


Fig.2

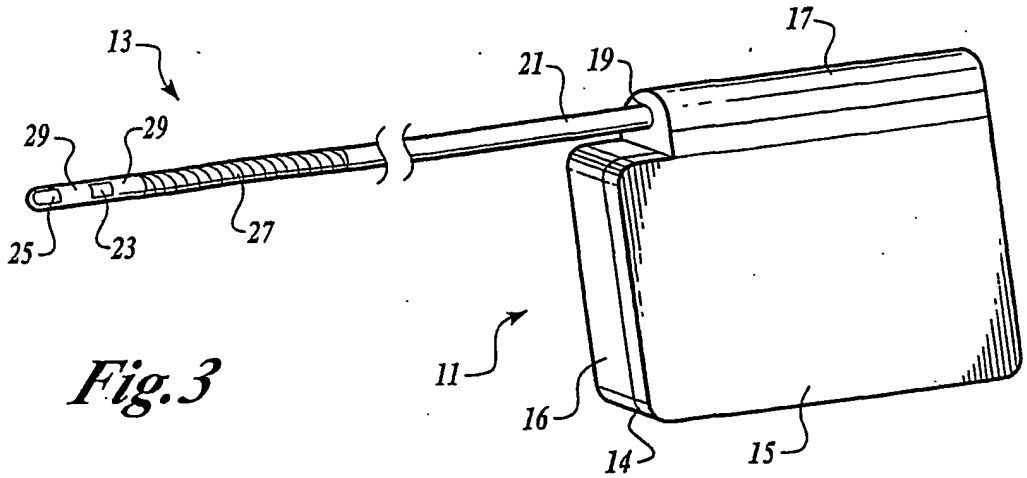


Fig.3

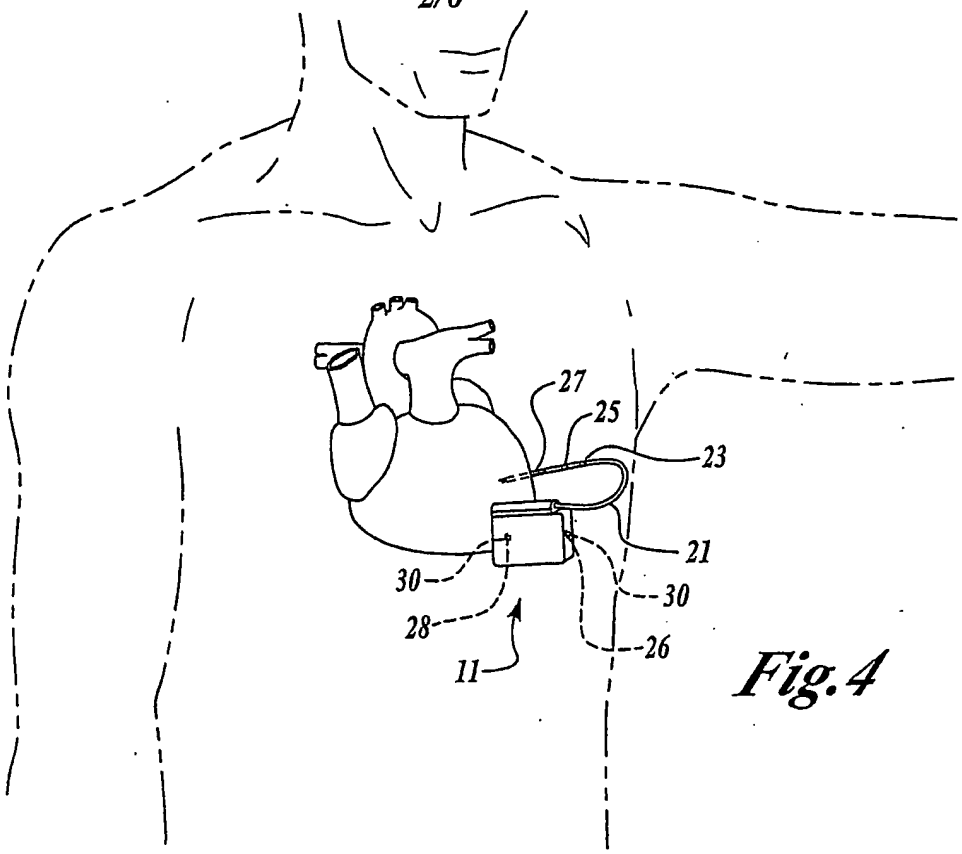


Fig. 4

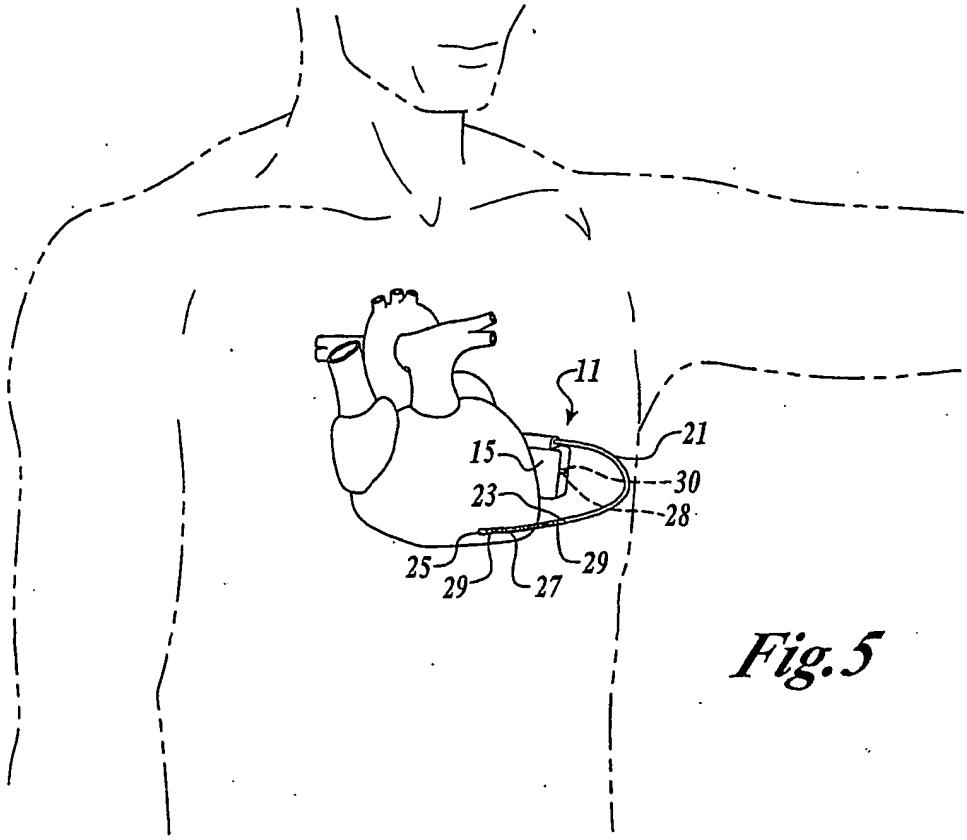


Fig. 5

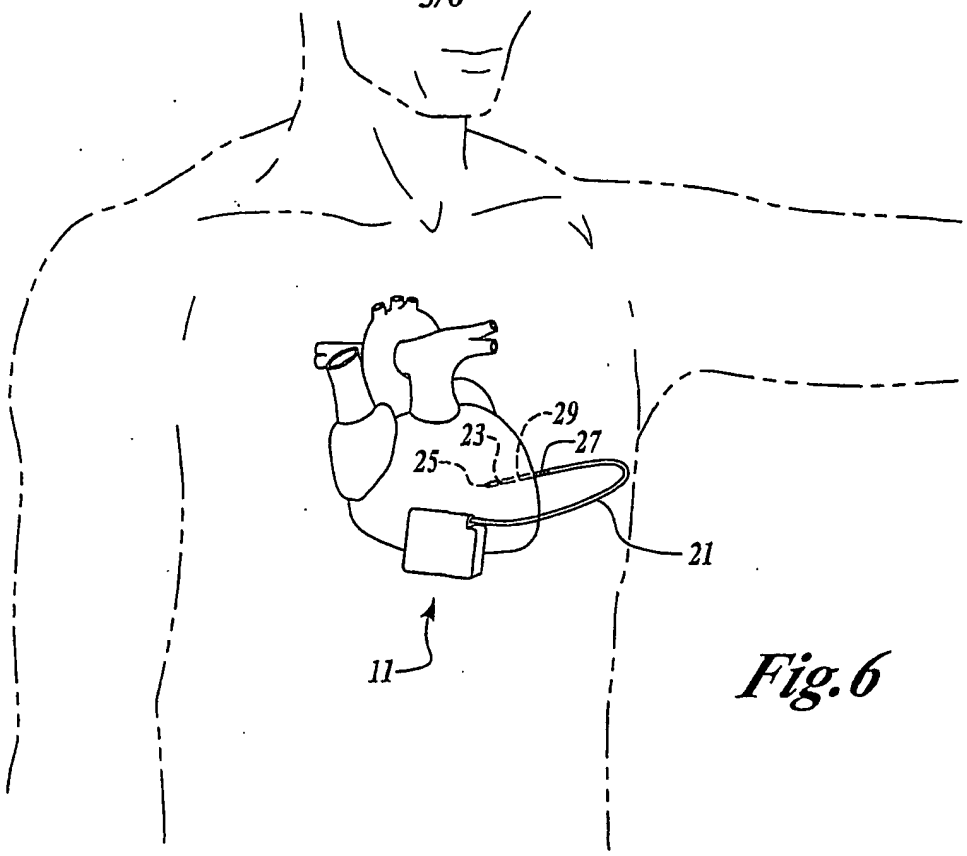


Fig.6

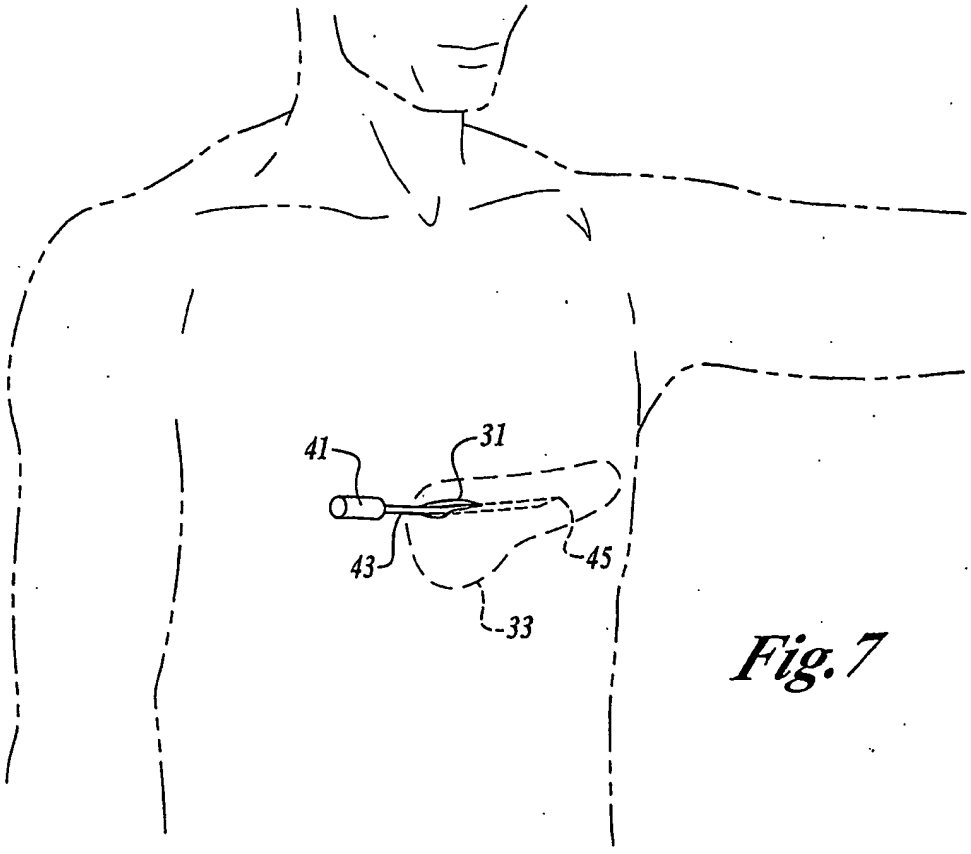


Fig.7

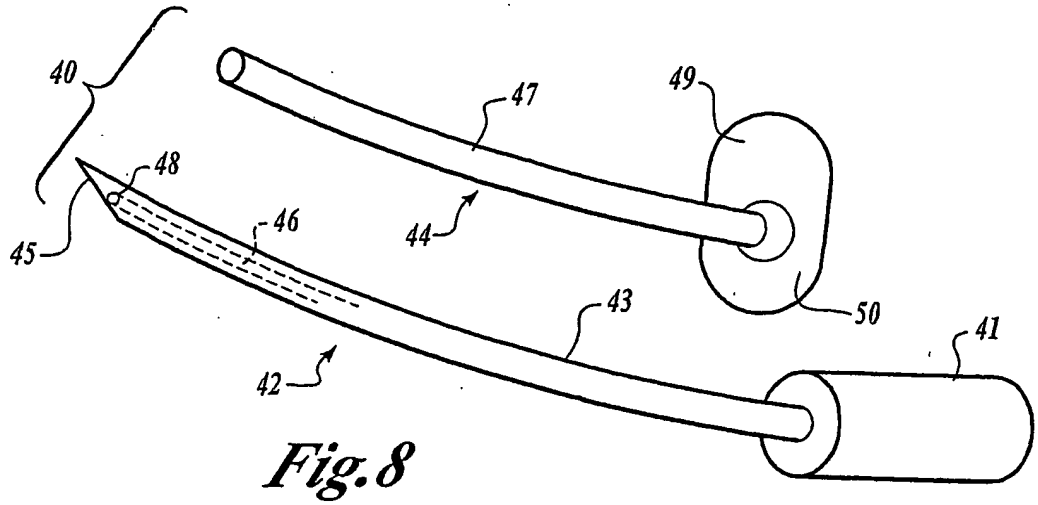


Fig.8

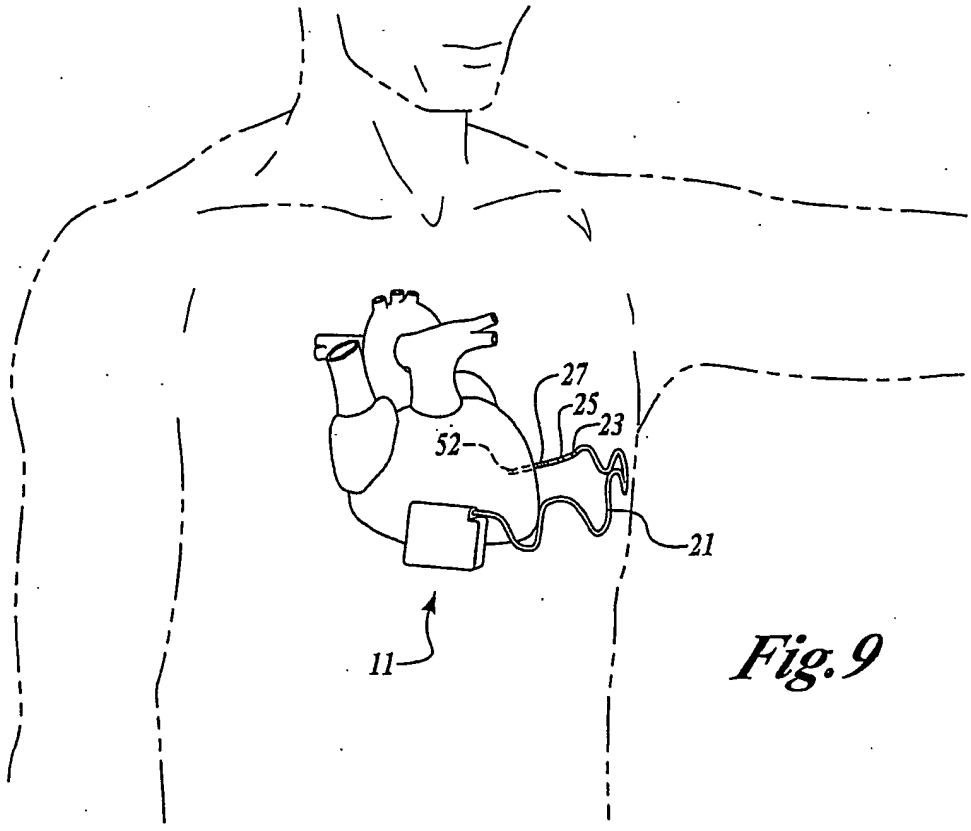


Fig.9

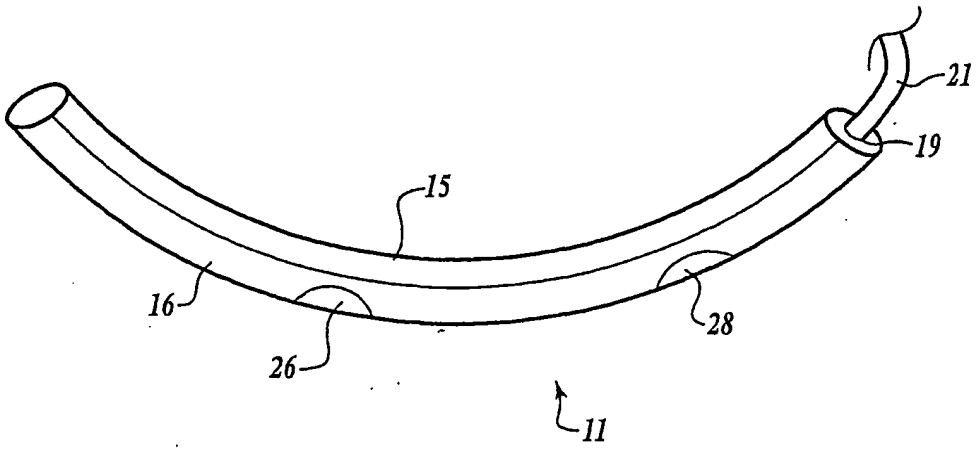


Fig.12

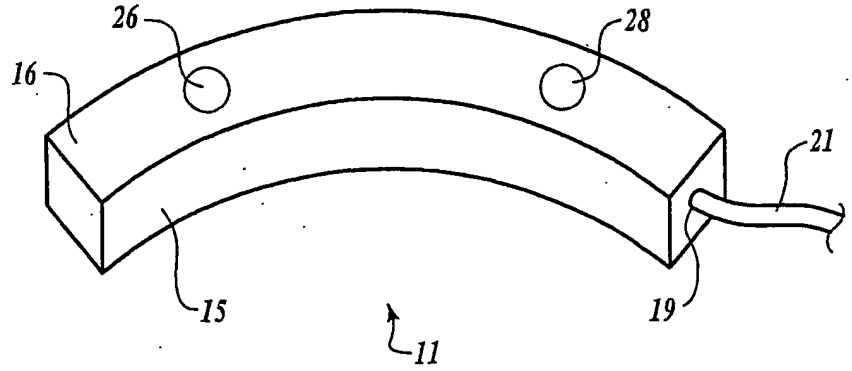
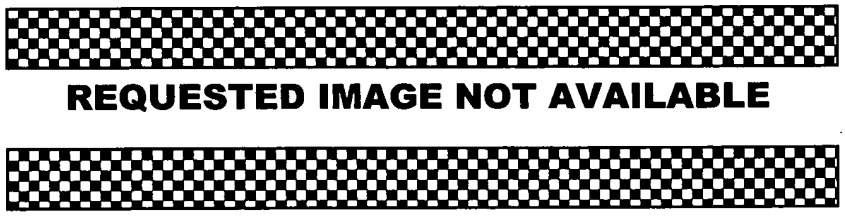


Fig.13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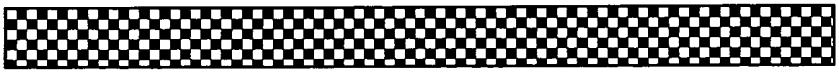

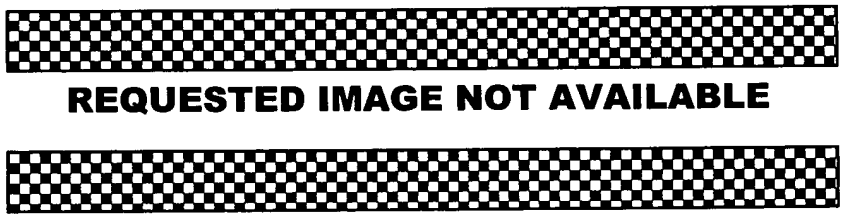
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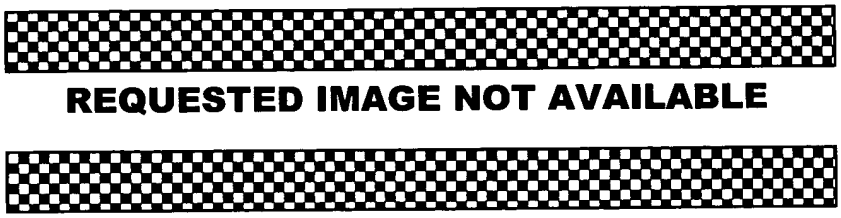
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